USSN: 09/933,316
Atty. Dkt. No.: 8600-0029
Client Ref No.: 01-185

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Examiner: Yong Soo CHONG
PORTER	Group Art Unit: 1617
Serial No.: 09/933,316	Confirmation No.: 7064
Filing Date: August 20, 2001	Customer No.: 20855
Title: EMBOLIC COMPOSITIONS WITH NON-CYANOACRYLATE RHEOLOGY MODIFYING AGENTS	

APPEAL BRIEF

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Appeal Brief, Commissioner for Patents, Alexandria, VA 22313 on **November 20, 2006**.

11/20/06 Michelle Hobson
Date Signature

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APPEAL BRIEF

Mail Stop Appeal Brief
Commissioner for Patents
Alexandria, VA 22313

Sir:

INTRODUCTION

Appellants submit one copy of their brief on appeal in accordance with Section 41.37 (69 Fed. Reg. 49962, Aug 2004). All claims were finally rejected under 35 U.S.C. § 103 in a Final Office Action dated March 27, 2006. A Notice of Appeal was received on August 7, 2006, making an Appeal Brief due on or before October 7, 2006. A two-month petition for extension of time accompanies this paper making a response due on or before December 7, 2006. Accordingly, this Appeal Brief is timely filed. Appellants respectfully request that the decision of the Examiner be reversed.

I. REAL PARTY IN INTEREST

Scimed Life Systems, the assignee of record of the above-referenced patent application, is the real party in interest in this matter.

II. RELATED APPEALS AND INTERFERENCES

Appellants are not aware of any related appeals or interferences.

III. STATUS OF THE CLAIMS

Claims 1, 3-4, 9-11, 15-28 and 38-41 are pending in the above-referenced case (hereinafter "the application") as shown in the Claims Appendix. Claims 2, 5 to 8, and 12-14 have been canceled. Claims 29-37 have been withdrawn from consideration. Claims 1, 3, 4, 9-11, 15-28 and 38-41 are appealed and were variously rejected under 35 U.S.C. § 103(a).

IV. STATUS OF THE AMENDMENTS

In response to the Examiner's Final Office Action mailed March 27, 2006, Appellants filed a Response with arguments and no amendments. An Advisory Action was mailed on July 13, 2006. Thus, all claims remained rejected for the reasons set forth in the Final Office Action and Advisory Action and have not been amended since the Final Office Action.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The subject matter of the appealed claims relates to vaso-occlusive compositions.

Independent claim 1 is drawn to a medical composition comprising a matrix-forming component comprising alkyl cyanoacrylate monomers, a stabilizer and a plasticizer (page 4, lines 5-7); a solid aggregate material comprising a radiopacifier (page 4, lines 7-10); and a polymeric non-cyanoacrylate rheology modifying agent that has an average molecular weight greater than 200,000, wherein the cyanoacrylate rheology

modifying agent is selected from the group consisting of poly(acrylates), poly(alkenes), poly(alkyl oxides), poly(amides), poly(carbonates), cellulosic polymers and copolymers, poly(dienes), poly(esters), poly(methacrylates), poly(saccharides), poly(siloxanes), poly(styrenes), poly(urethanes), poly(vinyl ethers), poly(vinyl esters), polymers and copolymers having high iodine content, and mixtures thereof (page 4, lines 10-11 and page 16, lines 6-15).

Dependent claim 3 further specifies that the solid aggregate material further comprises a second non-cyanoacrylate rheology modifying agent comprising an inorganic particulate material (page 18, lines 14-21). Claim 38 depends from claim 3 and specifies that the inorganic particulate material is selected from the group consisting of fumed silica, silicatious earth, bentonite, and mixtures thereof (page 17, lines 1-7). Dependent claim 39 specifies that the second non-cyanoacrylate rheology modifying agent of claim 3 is a particulate material comprising from greater than 0% to about 75%, by volume of the solid aggregate materials (page 18, lines 13-15). Dependent claim 40 specifies that the second non-cyanoacrylate rheology modifying agent of claim 3 is a particulate material comprising from greater than 0% to about 40%, by volume of the solid aggregate materials (page 18, lines 15-18). Dependent claim 41 specifies that the second non-cyanoacrylate rheology modifying agent of claim 3 is a particulate material comprises inorganic particles with surface-modifying molecules adsorbed to or bonded to the surfaces of said particles for improving the stability of a suspension of said particles within said composition (page 20, lines 11-25).

Dependent claim 4 further specifies that the non-cyanoacrylate rheology modifying agent of claim 1 is soluble in the alkyl cyanoacrylate monomers or in the plasticizer (page 16, lines 1-3).

Dependent claim 9 indicates that the non-cyanoacrylate rheology modifying agent of claim 1 and the plasticizer is the same material (page 16, lines 24-26).

Dependent claim 10 specifies that the non-cyanoacrylate rheology modifying agent comprises from greater than 0% to about 10%, by weight of the matrix-forming components (page 18, lines 8-10).

Dependent claim 11 indicates that the non-cyanoacrylate rheology modifying agent is a polymer comprises from about 1% to about 5%, by weight of the matrix-forming components (page 18, lines 10-12).

Dependent claim 15 specifies that the alkyl cyanoacrylate monomer of claim 1 is a compound of the formula $H_2C=C(CN)--C(O)OR$, wherein R is an alkyl group of about 1 to about 18 carbons (page 11, lines 2-5). Dependent claim 16 specifies that the R group of claim 15 is an alkyl group of about 4 to about 10 carbons (page 14, lines 7-10).

Dependent claim 17 specifies that the alkyl cyanoacrylate monomer of claim 1 is present in an amount of from about 20% to about 75%, by weight of the matrix-forming component (page 14, lines 13-15; 2nd row, 2nd column of Table on page 23).

Dependent claim 18 specifies that the alkyl cyanoacrylate monomer of claim 1 is present in an amount of from about 30% to about 70%, by weight of the matrix-forming component (page 14, lines 15-17; 3rd row, 2nd column of Table on page 23).

Dependent claim 19 specifies that the stabilizer of claim 1 is an inorganic acid, an organic acid, a free radical inhibitor, an antioxidant, or a mixture thereof (page 14, lines 18-31). Dependent claim 20 specifies that the stabilizer of claim 1 is present in an amount of from about 50 ppm to about 500 ppm (page 15, lines 25-27).

Dependent claim 21 specifies that the radiopacifier of claim 1 is selected from the group consisting of Ta, TaO, Au, Pt, Zr, ZrO, bismuth subcarbonate, and barium sulfate (page 20, lines 4-10).

Dependent claim 22 specifies that the radiopacifier of claim 1 is comprises radio-opaque particles with surface-modifying molecules adsorbed to or bonded to the surfaces of said particles for improving the stability of a suspension of said particles within said composition (page 20, line 11 to page 21, line 10).

Dependent claim 23 specifies that the radiopacifier of claim 1 is about 25% to about 100%, by volume of the solid-aggregate material (page 21, lines 25-27). Dependent claim 24 specifies that the radiopacifier of claim 1 is about 60% to about 100%, by volume of the solid-aggregate material (page 21, lines 27-29).

Dependent claim 25 specifies that the plasticizer of claim 1 is selected from the group consisting of organic esters containing 10 or more carbon atoms and polymeric compounds having a glass transition temperature less than 20°C (page 18, lines 22 to 32).

Dependent claim 26 specifies that the plasticizer of claim 1 is selected from the group consisting of aromatic esters, alkyl esters, phthalate esters, citrate esters, glycerol esters, plant derived oils, animal derived oils, silicone oils, iodinated oils, vitamins A, C, E, and acetates and esters thereof, and mixtures thereof (page 19, lines 4 to 11).

Dependent claim 27 specifies that the plasticizer of claim 1 is about 10% to about 75%, by weight of the matrix-forming component (page 19, lines 15-16). Dependent claim 28 specifies that the plasticizer of claim 1 is about 30% to about 60%, by weight of the matrix-forming component (page 19, lines 17-18).

VI. GROUNDS OF REJECTION

1. Claims 1, 3-4, 9-11, 15-28 and 39-41 were rejected under 35 U.S.C. § 103 as allegedly obvious over WO 00/44287 (hereinafter "Krall") in view of U.S. Patent No. 6,203,779 (hereinafter "Ricci").

2. Claims 1, 3-4, 9-11, 15-28 and 38-41 were rejected under 35 U.S.C. § 103 as allegedly over Krall in view of Ricci and further in view of U.S. Patent No. 4,997,861 (hereinafter "Hechenberger").

VII. ARGUMENTS

1. Claims 1, 3-4, 9-11, 15-28 and 39-41 Are Not Obvious Over Krall in view of Ricci

(a) Summary of the *Claimed* Subject Matter

As summarized above, the subject matter of the appealed claims encompasses compositions comprising the following combination of elements: (1) a matrix-forming component comprising alkyl cyanoacrylate monomers, a stabilizer and a plasticizer; (2) a solid aggregate comprising a radiopacifier; and (3) a polymeric **non**-cyanoacrylate

rheology modifying agent having a molecular weight greater than 200,000 and selected from the recited group. Thus, the particularly claimed subject matter does not encompass compositions of cyanoacrylate monomers without non-cyanoacrylate rheology modifying agents of the specified molecular weights (molecular weights >200,000).

While the Examiner has agreed throughout prosecution that Krall does not teach or suggest the combination of cyanoacrylate monomers and non-cyanoacrylate rheology modifying agents of greater than 200,000, the rejections are based on the allegation that the second reference (Ricci) does not "discourage" the combination and, in addition, somehow suggests the use of non-cyanoacrylate rheology modifying agents having a molecular weight greater than 200,000 (Advisory Action, page 2):

> Ricci merely uses alternative language for the usage of cyanoacrylates and non-cyanoacrylates, but does not discourage the combination of the two components. Nonetheless, the Ricci reference was employed to add only non-cyanoacrylate rheology modifying agents in the composition.
>
> ...the adjustment of the viscosity of the composition can be readily achieved by mere adjustment of the molecular weight of the polymers.

However, for the reasons of record, reiterated herein, Ricci does not suggest the desirability of combining cyanoacrylates and non-cyanoacrylates, which is required to establish a *prima facie* case of obviousness. Nor does Ricci suggest the desirability of non-cyanocrylate rheology modifying agents having molecular weights greater than 200,000, as set forth in the appealed claims. It is not enough to for the Office to show that a reference does not "discourage" a combination – the desirability of making the combination (including particular molecular weight limitations) must also be demonstrated.

(b) A *Prima facie* Case of Obviousness Has Not been Established

The Examiner bears the burden of establishing a *prima facie* case of obviousness. *See, e.g., In re Ryckaert,* 28 USPQ2d 1955, 1956 (Fed. Cir. 1993); and *In re Oetiker,* 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). In addition, the law is well settled that references

must teach all the limitations of the claimed invention and, moreover, suggest the desirability of arriving at the claimed subject matter. (*See, e.g., Amgen, Inc. v. Chugai Pharm. Co.,* 18 USPQ2d 1016, 1023 (Fed. Cir. 1991) stating that "hindsight is not a justifiable basis on which to find that the ultimate achievement of a long sought and difficult scientific goal was obvious;" *In re Laskowski,* 10 USPQ2d 1397, 1399 (Fed. Cir. 1989) stating that "the mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification" (emphasis added); and *In re Fulton*, 391 F.3d 1195 (Fed. Cir. 2004) stating that "[t]he question is whether there is something in the prior art as a whole to suggest the desirability").

In the pending case, the Examiner has not met this burden and the rejections cannot be maintained.

(c) The References Do Not Teach or Suggest All the Elements of the Claims

The Office has not met its burden of showing that the proposed combination of Krall and Ricci teaches or suggests all the limitations of the claims on appeal.

As admitted by the Office, there is nothing in the primary reference (Krall) about **non**-cyanoacrylate rheology modifying agents as claimed, let alone rheology modifying agents having molecular weights greater than 200,000.

For its part, Ricci does not teach or suggest multiple elements of the pending claims including (1) the molecular weight limitation of the claimed non-cyanoacrylate rheology modifying agents, (2) a composition that includes a solid cyanocrylate and/or (3) a composition that combines a cyanoacrylate and non-cyanoacrylate as claimed.

With regard to the molecular weight limitation, Ricci teaches that, at most, polymers having a molecular weight of 200,000 – there is nothing in Ricci about any polymers with molecular weights greater than 200,000 (Ricci, col. 5, lines 23-35):

> Preferred biocompatible polymers include cellulose diacetate and ethylene vinyl alcohol copolymer. Cellulose diacetate polymers are either commercially available or can be prepared by art recognized procedures. In a preferred embodiment, the number average molecular weight, as determined by gel permeation chromatography, of the cellulose diacetate

> composition is from about 25,000 to about 100,000 more preferably from about 50,000 to about 75,000 and still more preferably from about 58,000 to 64,000. The weight average molecular weight of the cellulose diacetate composition, as determined by gel permeation chromatography, is preferably from about 50,000 to 200,000 and more preferably from about 100,000 to about 180,000. As is apparent to one skilled in the art, with all other factors being equal, cellulose diacetate polymers having a lower molecular weight will impart a lower viscosity to the composition as compared to higher molecular weight polymers. Accordingly, adjustment of the viscosity of the composition can be readily achieved by mere adjustment of the molecular weight of the polymer composition.

Likewise, there is nothing in Ricci regarding the first component of the claimed combination (*i.e.,* a solid cyanoacrylate containing matrix). Indeed, all Ricci's components all fluid until they are administered (Ricci, Abstract, emphasis added):

> Disclosed are methods for treating endoleaks arising from endovascular repair of abdominal aortic aneurysms. The disclosed methods involve the in situ sealing of endoleaks after placement of an endovascular prostheses in the abdominal aorta. Sealing of endoleaks is achieved by injection of either a biocompatible polymer or prepolymer **fluid** composition into the endoleak which composition in situ solidifies to seal the leak. Preferably, the biocompatible **fluid composition** comprises a contrast agent to allow the clinician to visualize the sealing process.

Moreover, all of Ricci's compositions are made up of <u>one</u> biocompatible polymer (cyanoacrylate or, alternatively, non-cyanoacrylate polymers having a molecular weight of 200,000 or less).

Not only is it insufficient for the Examiner to assert that Ricci does not "discourage" the claimed combination, it is in error. In fact, Ricci discourages combining multiple polymers and also discourages combining fluids and solids.

Thus, all of the elements of the claimed subject matter are not found in Krall or Ricci, alone or in combination. Contrary to the Examiner's assertion, Applicants have not argued the references individually. Instead, Applicants have shown how Krall does not teach the element of non-cyanoacrylate rheology modifying agents and Ricci does not teach the claimed elements of (1) non-cyanoacrylate rheology modifying agents having a molecular weight greater than 200,000 (2) a composition that includes a solid

cyanocrylate and/or (3) a composition that combines a cyanoacrylate and non-cyanoacrylate. On this basis alone, the obviousness rejection cannot stand.

(d) There is No Motivation to Modify the References or to Combine them As Set Forth in the Rejection

Moreover, even assuming, for the sake of argument only, that the references teach or suggest all the claimed elements, there is no motivation to combine the references as set forth in the rejection.

In the instant case, the rejection is premised on at least three significant modifications to the references, namely (1) combining cyanoacrylate polymers and non-cyanoacrylate polymers into the same composition; (2) modifying Ricci's polymers to have molecular weights greater than 200,000; and (3) modifying Ricci's compositions to be solids. There is no motivation in the references themselves or in the state of the art to make these modifications.

With regard to combining cyanoacrylate polymers (Krall) and non-cyanoacrylate polymers (Ricci) in a single composition, the Examiner has continued to assert that the motivation to combine somehow derives from the notion that Krall and Ricci relate to "embolic" compositions. (Final Office Action, paragraph 5).

However, this is **not** a sufficient ground to support a *prima facie* case of obviousness. In fact, the record is clear that the claimed compositions, which include both alkyl cyanoacrylate monomers and non-cyanoacrylate polymers, represent a non-obvious improvement over compositions including only one of these polymers (*see, e.g.,* page 3, lines 18-20 and page 25, lines 15-25 of the specification):

> There is no suggestion or recognition [in Krall] that such properties can be improved by a non-cyanoacrylate rheology modifying agent. ...
>
> The composition has the desired viscosity and cohesive characteristics to administer into an ionic fluid environment, such as blood. The composition forms a solid structure upon contact with the ionic environment. ... The composition and method of present invention can be advantageously used to block blood flow to certain tissues, areas, or cavities in the vasculature.

As set forth in the specification, Krall does not in any way suggest adding non-cyanoacrylate rheology modifying agents to their cyanoacrylate resins.

For its part, Ricci also fails to suggest using non-cyanoacrylate polymers in the same composition as cyanoacrylate polymers. Indeed, Ricci draws a clear distinction between cyanoacrylate prepolymers and non-cyanoacrylate polymers such as cellulose diacetate – Ricci unambiguously teaches that they are used separately (Ricci, Abstract and col. 1, lines 11-14, emphasis added):

> Sealing of endoleaks is achieved by injection of **either** a biocompatible polymer **or** prepolymer fluid composition into the endoleak which composition in situ solidifies to seal the leak.

Ricci's teachings that cyanoacrylates and non-cyanoacrylates such as cellulose diacetate are distinct compositions that are to be used in the alternative is also mirrored in the claims of this patent – claim 1 is drawn to a fluid composition generally, claims 2-12 specify that the fluid composition is a biocompatible polymer; while claims 13-14 specify that the fluid composition include a biocompatible prepolymer.

As noted above, a *prima facie* case of obviousness cannot be established by showing that Ricci does not "discourage" combining cyanoacrylates and non-cyanoacrylates in the same composition, particularly when Ricci does in fact discourage the combination. (Advisory Action, page 2). The law requires that the desirability of the claimed invention be shown. The Examiner has not met this burden and cannot because there is nothing in Ricci that suggests that the claimed combination would be desirable.

In light of Krall's and Ricci's failure to suggest compositions including both cyanoacrylate and non-cyanoacrylate rheology modifying agents as claimed, there is no motivation to combine the references as set forth in the rejection and, accordingly, the rejection cannot be sustained.

Similarly, it is error to assert that it would have been obvious to the skilled artisan to modify the molecular weight of Ricci's rheology modifying agents to arrive at the rheology modifying agents having molecular weights greater than 200,000, as claimed.

In this regard, the Examiner continues to assert that the motivation to increase the molecular weight of the polymers disclosed in Ricci derives from the fact that increasing molecular weight was known to increase viscosity. (Final Office Action, paragraph 5)

However, Ricci is clear that 200,000 is the maximum average molecular weight of such cellulose diacetate polymers and that 200,000 provides more than sufficient viscosity (col. 5, lines 23 to 35 of Ricci, emphasis added):

> Preferred biocompatible polymers include cellulose diacetate and ethylene vinyl alcohol copolymer. Cellulose diacetate polymers are either commercially available or can be prepared by art recognized procedures. In a preferred embodiment, the number average molecular weight, as determined by gel permeation chromatography, of the cellulose diacetate composition is from about 25,000 to about 100,000 more preferably from about 50,000 to about 75,000 and still more preferably from about 58,000 to 64,000. The weight average molecular weight of the cellulose diacetate composition, as determined by gel permeation chromatography, is preferably from **about 50,000 to 200,000** and more preferably from about 100,000 to about 180,000.

When considered in context, it is clear that Ricci does not teach the "same" polymers because their molecular weights are different.

Furthermore, it is untenable to assert that the difference in molecular weight as between the claimed rheology modifying agents and Ricci's cellulose diacetates is either negligible or an obvious optimization of Ricci's polymers.

Ricci does not teach or suggest that the molecular weight of the cellulose diacetate and ethylene vinyl alcohol copolymers should ever exceed 200,000, for any reasons, including in order to increase viscosity. Rather, as clearly set forth above, by its own terms Ricci teaches that a molecular weight of no greater than 200,000 was sufficient to impart the desired viscosity for the intended embolic use, namely to stop leaks when used in combination with an endovascular prosthesis.

Furthermore, even if Ricci did teach polymers having a molecular weight greater than 200,000 (which it does not), there is still nothing the Examiner has pointed to in the references or state of the art generally that suggest combining cyanoacrylates and non-cyanoacrylates as claimed.

Thus, the cited references, and state of the art as a whole, do not teach or suggest each element of the claimed compositions. Nor has the Office met its burden of showing that the requisite motivation to: (1) modify Ricci's polymers to have higher molecular weights; and/or (2) combine these modified polymers with Krall.

The alleged motivation to combine (use as embolic compositions) is not present because none of the references teach or suggest advantages deriving from the combination. Without the benefit of Appellants' disclosure, a skilled artisan would have had no motivation and no reasonable expectation that modifying Ricci's rheology modifying agents to have molecular weights greater than 200,000 and then adding these agents to Krall's compositions would provide improved compositions, both in terms of embolic characteristics and delivery. Accordingly, a *prima facie* case of obviousness has not been (and indeed cannot be) presented by the Office, as such a rejection can only be based on improper hindsight reconstruction. Withdrawal of the rejection is in order.

(e) Secondary Considerations of Non-Obviousness: Unexpected Results

Furthermore, although not required because the Office has failed to present a *prima facie* case of obviousness, evidence regarding unexpected results is already of record.

For instance, the as-filed specification makes it clear that combining non-cyanoacrylate rheology modifying agents with known cyanoacrylate embolic resins significantly improves viscosity, cohesiveness, suspension of dense radiopacifiers, radiopacity, hydrolytic stability, adhesiveness to the target tissue and/or ease of delivery via microcatheter (decreases adhesiveness to the catheter). *See, e.g.,* as-filed specification, page 3, lines 22-30; page 7, lines 26-29; page 8, line 29 to page 9, line 5; and page 17, line 31 to page 18, line 7, which latter passage is reproduced below):

> A rheology modifying agent can impart properties of the liquid injectable composition, such as improved viscosity, improved cohesiveness, improved suspension, stability of dense radiopacifying powders and additional radiopacity. A solidified composition including a polymeric rheology modifying agent can have properties demonstrating improved hydrolytic stability when compared to cyanoacrylate compositions

containing pre-polymerized cyanoacrylate.

Thus, although a *prima facie* case of obviousness has not been made out (and indeed the references contain no supporting basis), additional factual evidence or record in the present case further supports to the non-obviousness of the claimed methods.

2. Claims 1, 3-4, 9-11, 15-28 and 38-41 Are Not Obvious over Krall in view of Ricci and further in view Hechenberger

For the reasons of record and as noted above, there is no combination of Krall and Ricci that render any of the claims on appeal obvious. Hechenberger does not cure the deficiencies of the combination of Krall and Ricci. Accordingly, claims 1, 3-4, 9-11, 15-28 and 38-41 are not obvious over Krall in view of Ricci and in further view of Hechenberger.

In sum, a *prima facie* case of obviousness has not been established. Krall and Ricci do **not** teach or suggest all the elements of the claims; there is no motivation to combine the references as suggested; and no combination that would result in the claimed compositions. Krall does not teach or suggest combining cyanoacrylates with non-cyanoacrylate rheology modifying agents as claimed. Ricci clearly teaches that cyanoacrylates and cellulose diacetate are to be used in separate composition and also teaches that the non-cyanoacrylate polymers have molecular weights less than 200,000. Accordingly, the skilled artisan would have no motivation to make the combination set forth by the Office. Hechenberger does not in any way make up for the deficiencies of Krall and Ricci. Therefore, without the benefit of Appellants' disclosure, a skilled artisan would have had no motivation to combine a matrix-forming component (alkyl cyanoacrylate monomers, a stabilizer and a plasticizer) with a solid aggregate material and a polymeric non-cyanoacrylate rheology modifying agent having a molecular weight greater than 200,000. The references do not teach all the claimed elements and the motivation to combine the references as set forth in the rejection is not present in the references themselves. Accordingly, the rejections under 35 U.S.C. § 103 should be withdrawn.

CONCLUSION

For the reasons stated above, Appellants respectfully submit that the pending claims are non-obvious over the cited references. Accordingly, Appellants request that the rejections of the claims on appeal be reversed, and that the application be remanded to the Examiner so that the appealed claims can proceed to allowance.

Respectfully submitted,

Date: November 20, 2006

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CLAIMS APPENDIX

Claims on Appeal:

1. (previous presented): A medical composition comprising

a matrix-forming component comprising alkyl cyanoacrylate monomers, a stabilizer and a plasticizer;

a solid aggregate material comprising a radiopacifier; and

a polymeric non-cyanoacrylate rheology modifying agent that has an average molecular weight greater than 200,000, wherein the cyanoacrylate rheology modifying agent is selected from the group consisting of poly(acrylates), poly(alkenes), poly(alkyl oxides), poly(amides), poly(carbonates), cellulosic polymers and copolymers, poly(dienes), poly(esters), poly(methacrylates), poly(saccharides), poly(siloxanes), poly(styrenes), poly(urethanes), poly(vinyl ethers), poly(vinyl esters), polymers and copolymers having high iodine content, and mixtures thereof.

2. (canceled).

3. (previously presented): The composition of claim 1, the solid aggregate material further comprising a second non-cyanoacrylate rheology modifying agent comprising an inorganic particulate material.

4. (previously presented): The composition of claim 1, wherein the non-cyanoacrylate rheology modifying agent is soluble in the alkyl cyanoacrylate monomers or in the plasticizer.

5 to 8. (canceled).

9. (original): The composition of claim 1, wherein the non-cyanoacrylate rheology modifying agent and the plasticizer is the same material.

10. (previously presented): The composition of claim 1, wherein the non-cyanoacrylate rheology modifying agent comprises from greater than 0% to about 10%, by weight of the matrix-forming components.

11. (previously presented): The composition of claim 1, wherein the non-cyanoacrylate rheology modifying agent is a polymer comprises from about 1% to about 5%, by weight of the matrix-forming components.

12 to 14. (canceled).

15. (original): The composition of claim 1, wherein the alkyl cyanoacrylate monomer is a compound of the formula H_2C=C(CN)--C(O)OR, wherein R is an alkyl group of about 1 to about 18 carbons.

16. (previously presented): The composition of claim 15, wherein the group represented by R is an alkyl group of about 4 to about 10 carbons.

17. (original): The composition of claim 1, wherein the alkyl cyanoacrylate monomer is present in an amount of from about 20% to about 75%, by weight of the matrix-forming component.

18. (original): The composition of claim 1, wherein the alkyl cyanoacrylate monomer is present in an amount of from about 30% to about 70%, by weight of the matrix-forming component.

19. (original): The composition of claim 1, wherein the stabilizer is an inorganic acid, an organic acid, a free radical inhibitor, an antioxidant, or a mixture thereof.

20. (original): The composition of claim 1, wherein the stabilizer is present in an amount of from about 50 ppm to about 500 ppm.

21. (previously presented): The composition of claim 1, wherein the radiopacifier is selected from the group consisting of Ta, TaO, Au, Pt, Zr, ZrO, bismuth subcarbonate, and barium sulfate.

22. (previously presented): The composition of claim 1, wherein the radiopacifier comprises radio-opaque particles with surface-modifying molecules adsorbed to or bonded to the surfaces of said particles for improving the stability of a suspension of said particles within said composition.

23. (previously presented): The composition of claim 1, wherein the radiopacifier is about 25% to about 100%, by volume of the solid-aggregate material.

24. (previously presented): The composition of claim 1, wherein the radiopacifier is about 60% to about 100%, by volume of the solid-aggregate material.

25. (original): The composition of claim 1, wherein the plasticizer is selected from the group consisting of organic esters containing 10 or more carbon atoms and polymeric compounds having a glass transition temperature less than 20°C.

26. (original): The composition of claim 1, wherein the plasticizer is selected from the group consisting of aromatic esters, alkyl esters, phthalate esters, citrate esters, glycerol esters, plant derived oils, animal derived oils, silicone oils, iodinated oils, vitamins A, C, E, and acetates and esters thereof, and mixtures thereof.

27. (original): The composition of claim 1, wherein the plasticizer is about 10% to about 75%, by weight of the matrix-forming component.

28. (original): The composition of claim 1, wherein the plasticizer is about 30% to about 60%, by weight of the matrix-forming component.

29. (withdrawn): A method of tissue bulking, filling, occluding or administering an embolic composition, comprising the steps of: a) providing alkyl cyanoacrylate monomers, a stabilizer, a plasticizer, a non-cyanoacrylate rheology modifying agent, and optionally a radiopacifier; b) mixing each component provided in step a) to form an embolic composition; and c) contacting the embolic composition with an ionic environment to render a solidified composition upon contact.

30. (withdrawn): The method of claim 29, wherein the embolic composition has an apparent viscosity of about 25 cP to about 2000 cP.

31. (withdrawn): The method of claim 29, wherein the embolic composition has an apparent viscosity of about 100 cP to about 300 cP.

32. (withdrawn): The method of claim 29, wherein the embolic composition demonstrates thixotropic, pseudo-plastic, or plastic behavior.

33. (withdrawn): The method of claim 29, wherein the solidified composition is hydrolytically stable.

34. (withdrawn): A method of embolizing a vascular space, comprising the steps of: a) providing alkyl cyanoacrylate monomers, a stabilizer, a plasticizer, a non-cyanoacrylate rheology modifying agent, and optionally a radiopacifier; b) mixing each component provided in step a) to form an embolic composition; and c) administering the embolic composition into a vascular space in a patient in a manner that contacts the composition with the blood of the patient.

35. (withdrawn): The method of claim 34, wherein the vascular space is an arteriovenous malformation, an aneurysm, a fistula, or a tumor.

36. (withdrawn): The method of claim 34, wherein the step of administering the embolic composition stabilizes or mitigates rupture of an aneurysm.

37. (withdrawn): The method of claim 36, wherein the aneurysm is a brain aneurysm.

38. (previously presented): The composition of claim 3, wherein the inorganic particulate material is selected from the group consisting of fumed silica, silicatious earth, bentonite, and mixtures thereof.

39. (previously presented): The composition of claim 3, wherein the second non-cyanoacrylate rheology modifying agent is a particulate material comprising from greater than 0% to about 75%, by volume of the solid aggregate materials.

40. (previously presented): The composition of claim 3, wherein the second non-cyanoacrylate rheology modifying agent is a particulate material comprising from greater than 0% to about 40%, by volume of the solid aggregate materials.

41. (previously presented): The composition of claim 3, wherein the second non-cyanoacrylate rheology modifying agent is a particulate material comprises inorganic particles with surface-modifying molecules adsorbed to or bonded to the surfaces of said particles for improving the stability of a suspension of said particles within said composition.

EVIDENCE APPENDIX

No documents are submitted in the Evidence Appendix

RELATED PROCEEDINGS APPENDIX

As noted above on page 2 of this Brief on Appeal and pursuant to 37 C.F.R. § 41.37(c)(i) and (c)(x), Appellants are not aware of any related appeals or interferences which may be related to, directly affect, be directly affected by, or have any bearing on the Board's decision in the pending appeal. Accordingly, no documents are submitted with this Appendix.